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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/279,275	07/22/94	WEINER	H 101016104051

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18M1/1211

EXAMINER
ACHUTAMURTHY, P.

ART UNIT	PAPER NUMBER
1818	44

DATE MAILED: 12/11/96

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/279,275

Applicant(s)

Weiner et al

Examiner

P. Achutamurthy

Group Art Unit

1818



☒ Responsive to communication(s) filed on Sep 9, 1996

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 2, 9, 11-13, 15-18, and 20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, 9, 11-13, 15-18, and 20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

Claim Rejections - 35 USC § 112

Rejection A

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the previous office actions issued during the prosecution of the parent application serial number 07/460,852, Paper No. 24, see page 3..

Claims 1,2, 9, 10-13, 15-18 and 20 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claim Rejections - 35 USC § 103

Rejection B

Claims 1, 2, 9, 11-13, 15-18 and 20 are rejected under 35 U.S.C. § 103 as being unpatentable over Campbell et al in view of Whitaker et al and/or Nalge-Anderson et al for the reasons of record in the office action of 09/22/93, Paper No. 24 and the office action of March 3, 1996, Paper No. 37.

Claim Rejections - 35 USC § 112

Rejection C (New)

Claims 1, 2, 9, 11-13, 15-18 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims have been amended to recite that the suppression of the autoimmune response comprises elicitation of suppressor T-Cells specific to the autoimmune disease being treated. Applicants refer to page 8, paragraphs 1 and 2. However the mater disclosed on these locations do not point any prior art reference or experimental data that would show that administration of an autoantigen would elicit suppressor T-Cells. It is not clear how the statement, for example, "the oral administration of MBP to rats induces suppression of immune responses to MBP" can support the elicitation of suppressor T-Cells specific for a given autoimmune disease. Applicants are requested to clarify.

Response to Amendment

Applicant's arguments filed September 9, 1996 have been fully considered but they are not persuasive. .

With respect to rejection A it is initially noted that the previous examiner's concern with respect to the differences in dosages used in the studies on rats in treating EAE and dosages used for human clinical trials is not maintained in view of applicants arguments. With respect the enablement of the claims for treating any autoimmune disease by the oral administration of a corresponding autoantigen applicants' arguments are not convincing for the following reasons. Although applicants have shown either in the present specification, in related priority applications or via experimental showings in declarations filed in this application, that certain specific diseases such as multiple sclerosis, rheumatoid arthritis, uveoretinitis, it is still not seen how such showings can support the present claims which very broadly call for treating any autoiimmune disease by the administration of a corresponding autoantigens because there are numerous autoiimmune diseases with different etiologies and different clinical symptoms. Furthermore applicants' arguments with respect to rejection B and the declaration of Dr. Toyka suggest that there are differences in the animal models used to study autoimmune diseases and their treatment and treatment of the same diseases in human subjects. Reference is made to applicants' comments made in the paragraph bridging pages 23 and 24 of the present response; and the paragraph bridging page 7 and 8 , and paragraph 19 on page 11 of Dr. Toyka's Declaration. Applicants are urged to consider limiting the present claims to those specific autoimmune diseases for which they have actually

provided a probative evidence of treatment in human subjects or evidence of art-acceptable correlation of animal models to human treatments.

With respect to rejection B, the main argument appears to be that none of the applied prior arts or their combination teaches or suggests the claims which require that the suppression of the immune response comprises elicitation of T-Cells. In this context the arguments advanced by the applicants and the Declaration of Toyka are found to be convincing; however the rejection is maintained because of a lack of adequate support for the limitation related to elicitation of suppressor T-Cells, as outlined in rejection C.

The information provided by the applicants regarding the pending related applications is greatly appreciated. Although no new rejections based on any conflicting subject matter between this application is now given, it would appear that potential for obviousness-type double patenting exists in the event any of the

copending applications containing conflicting claimed subjected matter are allowed before this application is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

Note : The location of the art unit handling this application is now **1818** . Please be sure to indicate the correct art unit in future papers filed in this application to facilitate their timely entry.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Achutamurthy whose telephone number is (703) 308-3804. The examiner can normally be reached on Monday-Thursday from 7:00 am to 6:00 pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The fax phone number for this Group is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

pa
December 13, 1996


PONNATHAPURA ACHUTAMURTHY
PRIMARY EXAMINER
GROUP 1800